

### REMARKS

Responsive to the Office Action mailed May 6, 2005, the present paper is timely filed on or before August 6, 2005. By the present paper and pursuant to the requirement set-out in the Office Action, claims 1 - 32 and 36 - 32 are cancelled without prejudice or disclaimer of subject matter therein. Also by the present paper, claims 33 and 34 are amended. Accordingly, claims 33, 34, and 35 are under examination. Entry of the amendments and reconsideration of the Application are respectfully requested.

#### The Claim Amendments

Claim 33 is amended to point out with even greater particularity that which Applicants consider to be their invention by reciting that the solvent is a water-miscible solvent. Support for the amendment can be found in the specification at, for example, page 6, line 22 to page 7, line 3.

Claim 34 is amended to make it consistent with claim 33 from which it depends.

#### Claim Rejections Under 35 U.S.C. § 102(b)

Claim 33 was rejected as allegedly anticipated by each of Francis G. Spinale, United States Patent 5,541,209 (the '209 patent); Robert J. Ardecky et al., United States Patent 5,310,929 (the '929 patent); and Claude Bernhart et al., United States Patent 5,270, 317 (the '317 patent). Because none of the applied art teaches all of the elements (limitations) of Applicants' claim 33, arranged as Applicants arrange them, Applicants respectfully traverse.

A claim is anticipated by a reference only if each and every element (limitation) set forth in the claim is found in the reference. Moreover, the elements must be arranged as required by the claim. M.P.E.P. § 2131.01 (underscore added).

In the '209 patent (Spinale), a solution of 2-butyl-3-[2'-(1-trityl-1H-tetrazol-5-yl)biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one is provided in a mixture of methanol and THF. The solution is acidified and thereafter evaporated to a residue. The solution, in substantially the same solvents in which the solution was provided, is not neutralized and filtered to separate trityl alcohol, as required by claim 33. The residue in the '209 patent is dissolved in water, and, ultimately, the product is obtained from ethyl acetate. Whether the Office attempts to correlate the aqueous solution or the ethyl acetate solution

with Applicants' provided solution, the correlation fails because the skilled artisan at the time the present application was filed would have known that ethyl acetate is not a water miscible solvent and neither solution of the '209 patent is obtained in the manner required by Applicants' claim 33.

Because the '209 patent does not teach all of the elements of Applicants' claim arranged as required by the claim, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Concerning the rejection over the '929 patent, Applicants respectfully draw the Office's attention to the fact that the compositions and processes of the '929 patent are drawn to a compound that is not 2-butyl-3-[2'-(1-trityl-1H-tetrazol-5-yl)biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one or irbesartan. Rather the processes of the '929 patent operate on or produce compounds having an optionally esterified carboxyl group at the 2-position of the spiro[4.4]nonene ring. The '929 patent cannot be said to disclose all of the elements of Applicants' claim 33. Accordingly, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Concerning the '317 patent (Bernhart), the method described beginning at column 21, line 1 provides a solution of 2-butyl-3-[2'-(1-trityl-1H-tetrazol-5-yl)biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one in a mixture of dichloromethane and THF. Applicants respectfully submit that the skilled artisan of the day would not have considered a combination of DCM and THF to be a water-miscible solvent. Moreover, this solution is treated with sodium hydroxide [21:8]. Applicants respectfully submit that the skilled artisan of the day would not have considered treatment with base to be acidification, as required by Applicants' claim 33. The '317 patent does not teach acidification of a solution of 2-butyl-3-[2'-(1-trityl-1H-tetrazol-5-yl)biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one in a water miscible solvent. For at least this reason, Applicants respectfully submit that the rejection over the '317 patent is improper and should be withdrawn.

Moreover, the provided solution taught by the '317 patent is evaporated to obtain a residue and is neither neutralized post-acidification nor filtered, both required by Applicants' claim 33. To the extent that the '317 may disclose a "second solution", such second solution is in ethyl acetate, a solvent substantially different from the DCM/THF of the provided solution and not a water miscible solvent in any event. The skilled artisan at the relevant time would have recognized that the solvent of the second solution of Applicants' claim 33 is

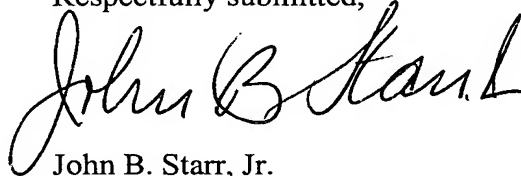
substantially the same as the solvent of the provided solution (with inclusion of components from acidification). Thus at least two other elements of Applicants' claim 33 are missing from or differently arranged in the teachings of the '317 patent. For this additional reason, Applicants respectfully submit that the rejection over the '317 patent is improper and should be withdrawn.

Conclusion

Based on the forgoing amendments and remarks, Applicants respectfully submit that the Application is in condition for allowance, which allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to telephone the undersigned attorney.

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Respectfully submitted,



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